Office of Pollution Prevention and Toxics, Chemical Right-to-Know Program HPV Challenge Program Frequently Asked Questions

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A compiled list of the most frequently asked questions about the HPV Challenge Program

What does a company/consortium need to do if they sell their share of a specific chemical to another company, or shut down operation of a specific chemical, during the course of the HPV program?

Companies which elect from the beginning not to sponsor specific HPV chemicals because they no longer manufacture or import them, even though they were associated with those chemicals in the past, can make their explanations a matter of public record by including them in their response to the Agency's invitation to participate in the HPV Challenge Program. Several companies have included such information in their initial responses to the Agency on the program. All HPV Challenge Program responses are posted to the ChemRTK website, linked to the name of the responding company.

Companies or consortia which commit to sponsor chemicals in the HPV Challenge Program will be expected to fulfill those commitments throughout the duration of the Program. Communications indicating that companies or consortia are withdrawing from specific chemical commitments will also be posted to the website, and chemicals on which commitments are not met will be considered in the development of future TSCA section 4 HPV test rules.

Since the November 9, 1999 Stakeholder meeting, there has been some confusion on the deadline for signing up for the voluntary phase of the HPV Challenge Program. Is December 1, 1999 still the deadline for "signing up" for the voluntary phase?

Yes.

In response to a question at the November 9, 1999 Stakeholder meeting, EPA indicated that if a "viable commitment" is received after the multi-chemical test rule is proposed but before the rule is final, the Agency would have little reason for finalizing that chemical in the multi-chemical test rule. If this is true, couldn't I sign up for the voluntary program after the multi-chemical test rule is proposed and thereby keep that chemical from being included in the final rule?

No, a commitment received after December 1 will be considered a commitment to do the work in the *regulatory* phase of the program. It will not be considered a commitment to the *voluntary* phase of the program except for the two limited exceptions outlined in other questions below. A "viable commitment" to do the work under the regulatory phase would differ in many ways from a commitment to doing the work under the voluntary phase of the program. Work under the regulatory phase would include agreeing to meet all of the commitments for the voluntary program; plus:

provide evidence that work is underway and proceeding in a timely manner,
provide data required to complete the SIDS battery, in the time frame set by EPA in the proposed rule; and
submit to EPA full copies of all final study reports, in addition to robust summaries.

In the regulatory phase, EPA plans on including these chemicals in a final rule until such time as summaries and reports from all new studies and existing data are submitted and judged to be timely and adequate. If such a commitment is made and kept, and the information deemed adequate, EPA would not include that chemical in a final multi-chemical HPV test rule.

EPA will accept viable commitments that involve categories and SAR after December 1, 1999 which (1) are consistent with the guidance available on the website for commitments regarding categories and SAR under the voluntary program *and* (2) which provide the additional information indicated above, including full copies of all studies [which are being relied upon to demonstrate data adequacy.

EPA will also soon issue an Advanced Notice of Proposed Rulemaking (ANPR) which will outline the Agency's plans for proposing test rules under TSCA section 4 to develop data on those HPV chemicals for which unmet data needs remain.

Will a company still have an opportunity to sponsor chemicals under the ICCA's HPV initiative or to agree to sponsor a chemical under OECD's HPV program?

Yes. Such sponsorships would need to meet the obligations under those respective efforts, including the need to specify the start year and to commit to completing all work (including preparation of the SIDS Initial Assessment Report (SIAR)) expeditiously but no later than the end of 2004.

If EPA receives my commitment to the voluntary program shortly after the December 1 deadline, will EPA accept my commitment to be part of the voluntary program and remove the committed chemical(s) from the proposed multi-chemical test rule?

EPA recognizes that holiday mail and the number of commitments expected may result in a delay in receiving and processing commitments. For this reason, EPA will accept commitments for a short time beyond the December 1 deadline and will make every effort to remove those chemicals from the proposed multi-chemical test rule or the ANPR.

My company requested in a letter to the Agency that a chemical on the HPV Challenge Program chemical list be "delisted" because it is either no longer HPV or it is a chemical not warranting SIDS level testing but we have not yet received a response from the Agency.

Your company or consortium should soon hear from EPA on these requests. If a specific request is denied, EPA will offer a two-month grace period, following the date of EPA's response letter, to allow the company or consortium which made the request an opportunity to sponsor the chemicals under the voluntary program.

Are the chemicals sponsored under the HPV Challenge Program subject to the TSCA section 12(b) export notification reporting requirements?

A. Chemicals sponsored under the HPV Challenge Program are not subject to the TSCA section 12(b) export notification requirements unless they are subject to TSCA section 12(b) as a result of a separate action under TSCA sections 4, 5, 6, or 7. In other words, these chemicals would not be subject to TSCA section 12(b) simply by virtue of their being sponsored under the voluntary HPV Challenge Program. Any unsponsored chemicals included in a final TSCA section 4 test rule would be subject to TSCA section 12(b) export notification requirements.

Are companies which volunteer to develop or otherwise provide data on chemicals under the HPV Challenge Program able to seek reimbursement from other manufacturers of these chemicals?

A. There is no formal mechanism for reimbursement under the HPV Challenge Program, however EPA encourages collaboration with other producers via consortia formation to share costs of data development for the chemicals included in the HPV Challenge Program.

If unsponsored chemicals are included in a TSCA section 4 test rule, would persons subject to the rule be required to complete all of the required testing by 2004?

A. EPA will likely require that all testing for a specific chemical be completed within one year from the effective date of the final rule for that chemical. Therefore, for many unsponsored chemicals under the HPV Challenge Program, the testing and final report for that chemical may be required prior to 2004.

If I import an unsponsored chemical that is subsequently included on a TSCA section 4 test rule, would I have any obligations under the rule?

A: Yes, you would be subject to the rule because importers are considered "manufacturers" under TSCA (see TSCA section 3(7)). You would be required to submit a letter of intent to test or an exemption application (see testing procedural rule at 40 CFR 790.45). If you submit an exemption application, you may be required to reimburse the entity that conducts the testing.

What is the ICCA and what is involved in its HPV Initiative?

The International Council of Chemical Associations (ICCA) consists of representatives of chemical associations from the United States, Europe, Japan, Australia, Canada, Mexico, Brazil, New Zealand, and Argentina. ICCA has its own initiative on HPV chemicals. The ICCA has indicated that its Initiative evolved out of concerns regarding the OECD HPV Program, as well as other general concerns related to chemical testing and assessment, particularly in Europe. The ICCA Initiative calls for the testing and assessment of 1,000 “high priority” chemicals by the year 2004. The testing and assessment work will be tied in directly with the OECD SIDS Program. Completed dossiers will be submitted to OECD so that a screening level hazard assessment can be completed. OECD is working to restructure its program to accelerate its

process and handle the increased volume of information.

The chemicals for the ICCA Initiative will be drawn from OECD's list of approximately 4,100 HPV chemicals, with the following considerations:

Identifying HPV chemicals of common interest across OECD countries.
Identifying chemicals with wide dispersive uses or high exposure potential that may not have been picked up under other programs.
Consulting with OECD and non-OECD members, especially developing countries, and non-governmental organizations.

The breakdown of the sources of chemicals on the OECD HPV list consists of contributions from the United States (2,600), Japan (600), and the EU (2,500). ICCA is looking at the intersection of these three sets (approximately 850 chemicals), to be supplemented by approximately 150 other chemicals of concern in at least two regions. ICCA has indicated that it will complete its working list by April 1999, and encourage companies to commit by the end of calendar 1999 to work on those chemicals. ICCA wants to leave room open for new stakeholder input (e.g, from developing countries) and so may leave some flexibility in making the final selections to meet the 1000 chemical goal. ICCA recognizes that the hazard assessment is only a first step, but it will produce valuable data for prioritization and possible acceleration of risk assessments by governments and industry, which will ultimately serve as the basis for risk management actions.

What is the relationship between the OECD (SIDS) HPV Program, ICCA Initiative and the U.S. HPV Challenge Program?

There is considerable consistency among the OECD HPV Program, ICCA Initiative and U.S. HPV Challenge Program. All three programs:

- are focused on HPV chemicals
- are based on the OECD SIDS battery of testing
- include the steps of information gathering, test plan development, and conducting SIDS testing as needed to provide a complete set of SIDS testing
- allow the use of category approaches to group chemicals and the use of SAR analysis as an alternative to testing where scientifically acceptable.

The OECD HPV and ICCA Initiatives also include the step of preparing the SIDS Initial Assessment Report (SIAR) which provides a screening level assessment of chemical hazards and includes the reporting of limited exposure information on the HPV chemical. The submission of exposure information and the preparation of a SIAR are not required elements for participation under the US HPV Challenge Program although EPA encourages industry to include these elements in their submissions under the Challenge.

As described in the Framework document, chemicals which are handled under the OECD HPV Program are considered to be "sponsored" and need not be addressed under the U.S. HPV Challenge

Program. EPA has indicated that similar treatment will be accorded to chemicals which are sponsored under the ICCA Initiative. U.S. companies willing to perform the additional work under these other programs (providing exposure information and preparing a SIAR) may want to consider identifying their Challenge chemicals as contributions to either or both of the OECD HPV and ICCA Initiatives.

The Framework document states that the U.S. will continue to meet its OECD obligations for preparing SIARs and thus such sponsorship by companies would contribute to meeting that commitment. Such chemicals could also be handled as part of meeting industry's commitments under the ICCA Initiative. U.S. companies deciding to sponsor chemicals under the U.S. HPV Challenge could also identify those chemicals as U.S. contributions to the OECD HPV Program and/or the ICCA Initiative targets. The U.S. (and the companies) could thus receive "multiple credits" for handling the chemicals under the several programs, i.e., recognition for contributions under 2 or 3 programs rather than only the one contribution under the U.S. HPV Challenge Program.

How should I submit a commitment letter to participate in the HPV Challenge if I am making a Confidential Business Information claim, e.g., for the identity of my company?

As of this date, the Agency has received very few CBI requests associated with the HPV Challenge. If you are reasserting a CBI claim that you made with your original IUR submission, you will need to send two copies of your commitment letter. The one containing CBI will need to be clearly marked as such, with brackets around the specific information being claimed CBI (for example, the identity of your company associated with a particular chemical). Send that copy in a double envelope; the inside envelope should be marked "TSCA CBI, to be opened by addressee only." The outside envelope should have no such distinguishing markings besides this address: US EPA, Document Control Officer (7407), 401 M St. SW, Washington, DC 20460, Attn: HPV Challenge Program. The second copy should be sanitized to remove the CBI information and included in the same envelope with the CBI version that is sent to the Document Control Office.

My company will be participating in the HPV Challenge Program as a member of a consortium. Is it necessary for me to submit an individual letter on behalf of my company or is it sufficient to have the consortium send one letter on behalf of the participating companies that includes my company as one of the members?

Since little time remains for submission of commitment letters before the March 15 deadline, EPA will accept a letter from a consortium that lists the member companies as long as information consistent with that required for sponsorship is included in that letter, specifically: the member companies of the consortium, the chemical(s) the consortium is committing to sponsor under the Challenge (in the case of a category, the name of the category and its constituent chemicals), the CAS number(s) of the substances being sponsored, the start year for each chemical (or category), and a consortium contact name and phone number. While a consortium letter is provisionally acceptable for indicating sponsorship, EPA requires that each member company submit its own letter to the Agency by April 15, 1999, indicating its membership in the consortium, and specifying the start year for each chemical(s) or category and providing the corporate contact name and phone number. For

further guidance, please refer to the Agency's "Guidance on Confidentiality Claims Related to Company-Chemical Associations Under the HPV Challenge Program."

I understand that EPA has removed inorganics and polymers from the HPV Challenge Program Chemical List. I think certain chemicals my company manufactures are either polymers or inorganic substances, and should not be on the HPV Challenge Program Chemical List. What should my company do?

After a comprehensive review, EPA removed certain chemicals from the original October 9, 1998, HPV Challenge Program Chemical List because they were either inorganic substances or polymers. The scope of the HPV Challenge Program does not include polymers and inorganic chemicals. These substances were excluded from the reporting requirements of the Inventory Update Rule (IUR) of 1986 unless regulated by a TSCA section 4, 5(a)(2), 5(b)(4) or 6 rule or an order under section 5(e) or 5(f), as stipulated under 40 CFR 710.26. The current list, dated December 9, 1998, is located on the Chemical Right-to-Know (ChemRTK) website. The address is: http://www.epa.gov/opptintr/chemrtk/hpvchemlt.htm. If you believe that other polymers or inorganic substances remain on the List, please alert the Agency by providing a detailed explanation and we will review your request.

My company no longer manufactures some of the chemicals on the HPV Challenge Program Chemical List. Are these chemicals still subject to the HPV Challenge Program?

The Agency will consider removing non-polymeric, organic chemicals from the HPV Challenge Program when it has been established that the chemical is "no longer an HPV" chemical and is not likely to become an HPV chemical again. The Agency recently released draft guidance for verifying that a chemical is "no longer an HPV" chemical and is not likely to become an HPV chemical again, available on the ChemRTK website at http://www.epa.gov/opptintr/chemrtk/guidocs.htm. Written documentation demonstrating that the current aggregate national production volume of a chemical is substantially less than 1 million pounds per year and is likely to remain so is required as described in the draft guidance document. This justification must be provided for all U.S. manufacturers and importers of the chemical. If your chemical(s) are not polymers or inorganics and your letter does not establish that the chemicals are "no longer HPV," they will remain on the HPV Challenge Program Chemical List.

My company uses chemical X as an intermediate in on-site processes. Exposure is low or non-existent. If my company is considering sponsoring chemical X and adequate data are not available, should we still test chemical X even though we believe exposure is low because chemical X never leaves our facility?

Chemicals which meet the requirements for Closed System Intermediates as described in the recently released draft guidance document on this topic will be eligible for a reduced SIDS testing battery. Please check the ChemRTK website at http://www.epa.gov/opptintr/chemrtk/guidocs.htm to obtain a copy of this document. EPA's guidance is based on guidance found in section 3.6 of the Screening Information Data Set (SIDS) manual which concerns "intermediates contained in closed systems." As with the "no longer an HPV chemical" discussed above, the requirements for closed system

intermediate status must be met by all U.S. manufacturers and importers for a chemical to be eligible for a reduced level of testing.

Won't the HPV Challenge Program cause significant numbers of animals to be utilized in tests? Aren't there any alternatives to animal testing?

EPA is committed to examining alternative test methods to reduce the number of animals needed for testing, to reduce pain and suffering on the part of test animals, and to explore the availability and validation of non-animal test methods. The Agency has been active for several years in both domestic and international settings, exploring alternatives to animal testing.

In furtherance of these goals, the Agency has met with representatives of animal welfare interest groups to discuss their concerns and to obtain more detailed information regarding approaches for reducing the reliance on animal testing. EPA sponsored a Chemical Right-to-Know Workshop on December 16-17, 1998, designed to allow interested groups to refine details of implementation of the HPV Challenge Program. At the Workshop, the use of non-animal test methods was discussed and several potential options for including alternative tests in parallel with currently acceptable scientific protocols were introduced. EPA also participated in a conference sponsored by the Center for Alternatives to Animal Testing (CAAT) at Johns Hopkins University held on January 26-27, 1999, in Baltimore, MD, to address the availability of alternative test methods which might satisfy the toxicological endpoints being sought through the HPV Challenge Program. At that meeting, EPA discussed several approaches, including combining studies or use of different test methods, which could reduce animal usage. These approaches were also presented to and discussed by the OECD's Working Party on Existing Chemicals at a meeting in Paris on February 16-17, 1999. The U.S. paper presented to the OECD, entitled HPV Chemical Human Health Testing: Animal Welfare Issues and Approaches , proposes approaches which could be used to minimize and optimize animal usage when obtaining SIDS testing program data on High Production Volume (HPV) chemicals, while still generating needed high quality information. The paper is available on the ChemRTK website. Opportunities described in the paper include various reduction, refinement and replacement testing strategies, as well as the employment of existing chemical testing data, structure-activity relationships and the use of chemical categories to reduce the need for testing.

EPA plans to implement the approaches discussed in the OECD paper, although one of the new test methods requires additional development before a final decision could be made on its use. Other options, such as those discussed at the CAAT meeting, will be evaluated further by EPA as implementation of the HPV Challenge Program continues. However, most of these suggestions would require further work before they could be implemented. Until non-animal test methods are validated for purposes of regulatory acceptance, such methods cannot be relied upon in the HPV Challenge Program. If relevant non-animal test methods become validated and achieve regulatory acceptance during the implementation of the HPV Challenge Program, EPA will consider their immediate use in the program.

A lot of companies produce the same chemical I do. Should we all do the testing, or can we split the burden somehow? Does EPA have rules on this?

Companies producing the same chemicals are encouraged to form consortia and to contract among themselves to collectively obtain and submit data to the HPV Challenge Program. The members of each consortium would decide among themselves how to apportion the costs and duties of consortium membership; EPA does not impose any particular structure or formula on companies who choose to work cooperatively. Since the HPV Challenge Program is a voluntary program, EPA cannot require companies to work together if they don't want to do so. EPA is also developing a test rule under TSCA section 4 to require SIDS testing be conducted on chemicals not sponsored under the HPV Challenge Program. Data reimbursement procedures at 40 CFR 791 are available, although these provisions have never been applied to date.

My company is interested in utilizing Structure Activity Relationships in our test plan. Is there EPA guidance available on SAR?

SAR Guidance is currently under development and will be posted on the ChemRTK website as soon as it is available.

How do I get the Agency to consider additional candidates for low priority designation on the HPV Chemical List, beyond those chemicals which have already received an Indicator of "1" ("not considered a candidate for testing under the HPV Challenge Program, based on preliminary EPA review indicating that testing using the SIDS base set would not further our understanding of the chemical's properties")?

The HPV Challenge Program Chemical List includes an indicator variable of "1" that, if present, signifies that the chemical is not considered a candidate for testing under the HPV Challenge Program, based on preliminary EPA review indicating that testing using the SIDS base set would not further our understanding of the chemical's properties. In order for EPA to consider other chemicals for the "1" indicator, a company or trade association must provide the technical rationale for such a designation. This would take the form of a review of the available information which shows that, for a given chemical, conducting the SIDS battery of tests would not be of value in furthering our understanding of the chemical's properties, including physical/chemical, environmental fate, environmental toxicity and mammalian toxicity endpoints. Alternatively, for well-tested chemicals, companies may want to provide the information in a test plan with robust summaries of the data, which would indicate no testing is required. In so doing the company would get credit for sponsoring the chemical in the HPV Challenge Program. They could also nominate it as a U.S. contribution for the OECD SIDS program to obtain international recognition of the hazard assessment prepared for that purpose.

My company manufactures a chemical which is used as a food additive. Why doesn't my chemical have an indicator of "1" on the HPV Challenge Program Chemical List?

Some of the chemicals on the HPV Challenge Program Chemical List have food additive, drug, or cosmetic uses, and, thus, are subject to Food and Drug Administration (FDA) requirements for these respective uses. However, these chemicals, which may have been approved by FDA for specific uses, may still have SIDS data gaps in areas which may not be germane to food additive, drug or cosmetic

uses, e.g., environmental fate and environmental toxicity, which are of concern to EPA and are required under the HPV Challenge Program. These endpoints may not have been taken into account for food additive, drug or cosmetic reviews. In addition, exposure scenarios different from those considered in the FDA review (e.g., occupational exposures in manufacture or use, or releases of the chemicals to the environment from industrial manufacturing sites) may have the potential to cause adverse impacts on health or the environment. Furthermore, chemicals which are approved by FDA for certain uses may have been fully tested for a number of SIDS endpoints (or in other related areas beyond SIDS testing, for example, carcinogenicity), but until those data are made publicly available, the goals of the HPV Challenge Program will remain unmet, and, furthermore, judgment cannot be made concerning the possible human or environmental risks presented by different exposures.

However, a manufacturer that submitted data to one agency could submit that information to the EPA in form of a robust summary and thus allow it to become publicly available under the HPV Challenge Program.

I believe that naturally-occurring substances are exempt from IUR reporting, and, therefore, should not appear on the HPV Challenge Program Chemical List. Does Natural Gas fit this exclusion?

40 CFR 710.26 exempts from IUR reporting any naturally occurring chemical substances manufactured by the manual, mechanical or gravitational means described in 40 CFR 710.4(b). Persons who separate or fractionate raw natural gas and/or any of the liquid streams produced from raw natural gas into more specific fractions by various combinations of heat, refrigeration, and/or absorption must report each stream so manufactured. Separation methods involving a change in physical state (i.e., liquid to gas or vice versa, etc.), such as distillation or refrigeration, are not considered simple mechanical processes by the Agency. Therefore, the resultant products of these methods are reportable under the IUR and are therefore included in the HPV Challenge Program.

I know that other companies must be producing the same chemicals I make, but I don't know who they are. How can I find them to see if we could combine resources and work together?

The Agency is developing databases to make non-confidential information from the 1990 and 1994 Inventory Update Rule (IUR) reporting cycles available through the ChemRTK website. These databases will include the non-confidential business information (non-CBI) identification of the companies which make or import chemicals on the HPV Challenge Program Chemical List. Watch the website for notification that this information is available. This information may not be complete, however, because companies may have claimed some of their manufacturing or importing information on HPV chemicals as CBI. If your industry has a trade association, they may be able to help you in identifying other trade association members as well.

My company mistakenly reported under the 1990 IUR for chemical X. Can we amend our IUR filing and get the chemical taken off the HPV Challenge Program List, or get our company off the list of companies invited to participate?

As discussed in the "No Longer HPV" guidance document, EPA has received 1990 IUR corrections from companies which also request that either: (1) the chemical(s) in question be removed from the HPV Challenge Program Chemical List or (2) the company in question not be held responsible for the chemical(s) under HPV Challenge Program. We have received requests to amend 1990 IUR filings because a company presently asserts that its 1990 IUR filing was in error because of: improperly reported impurities, improperly reported byproducts, improperly reported naturally occurring substances, or improperly reported wastes.

Reporting for the 1990 IUR is over 8 years old. Accordingly, the Agency will not devote substantial resources to processing new corrections to the 1990 IUR and constantly changing the HPV Challenge Program List. Companies can submit corrections to the 1990 IUR, but those submissions will not affect the HPV Challenge Program Chemical List. Instead, EPA has provided processes for companies to identify chemicals that are "no longer HPV" (see FAQ #2 above) and should not be considered subject to the Program. The List will be annotated to identify chemicals which as "no longer HPV."

Companies who indicate that they reported in error will not be removed from the list of companies who were invited to participate in the HPV Challenge Program, because that list is a matter of public record. All response letters are being posted to the website, however, so the reasons offered for limited or non-participation in the Program will also be a matter of record.

Are we still subject to the HPV Challenge Program if...

My company sells or we are:
specialty products
a marketer & distributor
a distributor
OR we
sold company
do not manufacture or import chemicals
are not a manufacturer or importer
are not engaged in a chemical related business, i.e., we are a power company
don't currently manufacture or import chemicals
are a subsidiary of another company which is participating or has responded to the Carol Browner invitation letter?

We would like to note that participation in the HPV Challenge Program is entirely voluntary. Technically, under the HPV Challenge Program, you are being asked to sponsor those HPV chemicals on the list which you currently manufacture or import. However, we welcome and encourage the participation of processors, users and others who distribute these HPV chemical substances in commerce, and expect that companies with active product stewardship programs (under, for example, Responsible Care«) will recognize the importance of filling basic data needs on the chemicals they use. EPA intends to issue TSCA section 4 test rules which will serve as a back-up for those chemicals not sponsored under the HPV Challenge Program. These test rules will apply to everyone who manufactures, imports, or processes the chemicals covered by the rule, so even if you don't normally think of yourself as a manufacturer, you may be subject to the

requirements of the Test Rule.

I use chemicals, but I don't make and sell them; I just wind up with wastes and byproducts that I have to report. Why did I get a letter calling me a "manufacturer?" I don't have to participate in this, right?

The definition of "manufacturer" in the Toxic Substances Control Act (TSCA) is very broad. It includes anyone who imports, manufactures, or produces chemicals. It doesn't matter whether those chemicals are being produced deliberately for sale or accidentally as a byproduct of or intermediate in some other process: the act of producing or importing a chemical makes you a manufacturer of that chemical under the statute.

Participation in the HPV Challenge Program is purely voluntary, and, while we encourage broad participation, no one has to respond to the invitation. When the HPV Test Rule is issued, however, it will apply to everyone who manufactures, imports, or processes the chemicals covered by the rule, so even if you don't normally think of yourself as a manufacturer, you may be subject to the requirements of the Test Rule.

My chemical should have had lots of testing completed, and I believe it was even found to be a carcinogen. Why does it have an Indicator 2 on the HPV Challenge Program chemical list? Why does there still need to be more testing on the chemical?

An Indicator of 2 means that the chemical is otherwise being handled under the Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) Program. As such, companies are not expected to sponsor these chemicals under the HPV Challenge Program and that is why your chemical has an Indicator of 2.

The goal of the HPV Challenge Program is to ensure that completed SIDS data are available for HPV chemicals - this can be met through existing studies or new testing. A key point is that at the end of the process, a set of SIDS data will be publicly available for all US HPV chemicals. Companies can get an idea of how much data are available by consulting EPA's analysis of publicly available data (found under www.epa.gov/opptintr/chemtest/ushpvweb.pdf) or that prepared by CMA, titled "Public Availability of SIDS-Related Testing Data For U.S. High Production Volume Chemicals." You can get a copy of this report by contacting CMA Publications at 301-617-7824. The report order number is #610336 and the report must be purchased. CMA's web address is http://www.cmahq.com. Offering to sponsor a chemical under the HPV Challenge Program does not necessarily mean that you would be conducting new testing. However, if the available data do not include all SIDS endpoints, then further testing will be needed.

Should importers of chemicals sponsor HPV chemicals too, or just manufacturers?

Both importers and manufacturers of chemicals on the HPV Challenge Program Chemical List are being asked to sponsor chemicals under the Program. EPA encourages importers to approach their international manufacturers/suppliers to either make publicly available existing test data or contribute towards conducting any new testing which is needed to complete the SIDS testing battery

for a particular chemical. In addition, the International Council of Chemical Associations (ICCA), made up of chemical trade associations from the U.S., the European Union, Japan, Canada, and elsewhere, has committed to a SIDS testing and assessment program which is compatible with the HPV Challenge Program. Note that if a chemical is included in the HPV test rule, manufacturers, importers and processors will be included among the persons subject to the test rule.

What if I import mixtures containing HPV chemicals?

Importers of chemicals on the HPV Challenge Program List, either isolated or as part of a mixture, are being asked to sponsor those chemicals in the Program and would be subject to the HPV test rule.

Can individual Chemical Divisions within a single corporation participate in the HPV Challenge Program?

Yes, as long as the parent corporation is identified, individual divisions within a company can sponsor a chemical. It is critical, however, that someone in a position of authority actually commits the company/division to the testing. Furthermore, multiple sponsor letters from the same parent company may be submitted. top

How will EPA be able to assess the large volume of test data that are expected to be submitted under this Program? The Agency is not looking to be the gatekeeper or bottleneck in releasing information received under the HPV Challenge Program. EPA plans to review all of the submitted information but will not delay posting of the test results while it conducts its evaluation. Thus, we plan to put all information, reviews, etc. up on the Internet (www.epa.gov/chemrtk) for interested parties to review.

My chemical is on the HPV Challenge Program Chemical List, but I manufacture or import less than one million pounds of that chemical. Should I still participate?

Yes, you should. Chemicals became "HPV" based upon a cumulative assessment of all IUR submissions for 1990 and test data need to be generated if necessary and made publicly available for these chemicals. If you reported manufacture and/or importation volume under the 1990 IUR for a HPV chemical your production volume contributed to that total. Note that the TSCA section 4 test rule, which will serve as a back-up for those tests not sponsored under the HPV Challenge Program, will cover persons that manufacture, import, or process one or more of the HPV chemicals.

I am a processor of a HPV chemical. Should I also participate in the HPV Challenge Program, or is that only for manufacturers or importers?

Yes. Although processors were not formally asked to, you should consider participating. We welcome and encourage participation of all persons that manufacture, process, use, or distribute these HPV chemical substances, and expect that companies with active product stewardship programs will recognize the real importance of filling basic data needs for these chemicals. Note that the TSCA section 4 test rule, which will serve as a back-up for those chemicals not sponsored under this

Program, will cover persons that manufacture, import, or process one or more of the subject HPV substances.

How does the "Children's Health" Test Rule (CHTR) relate to this program?

The CHTR complements the HPV testing efforts in the ChemRTK program, but goes beyond the basic SIDS screening level testing for a selected group of about 50 chemicals based on concerns for children as a potentially more sensitive population and with effectively greater exposures than adults. This rule will require the testing of chemicals about which we lack toxicity data needed to more fully assess the risk of human exposure. The rule will require testing by persons that manufacture, import, or process one or more of the selected chemicals.

How much will the CHTR expand requirements beyond SIDS? What will the testing requirements be? What is the estimated cost?

In the CHTR, EPA is planning to propose a battery of 12 tests, three of which overlap with SIDS. If there is overlap between chemicals sponsored under the HPV Challenge Program and chemicals subject to the proposed CHTR, the three SIDS tests which overlap between the HPV Challenge Program and the CHTR will be dropped from the final CHTR, for those particular chemicals sponsored under the HPV Challenge Program. Following are the 12 tests in the CHTR; the three tests which overlap with SIDS are noted with an asterisk.
*Acute toxicity in rodents
*Bacterial reverse mutation assay
In vitro mammalian cell gene mutation test in L5178Y mouse lymphoma cells
*In vivo chromosomal aberration OR in vivo micronucleus test
Prenatal developmental toxicity study
Reproduction and fertility effects
Developmental neurotoxicity study
Metabolism and pharmacokinetics
90-day subchronic in rodents
Neurotoxicity screening battery
Immunotoxicity
Combined chronic/carcinogenicity OR Carcinogenicity

The SIDS tests for repeat dose toxicity, developmental toxicity and reproductive toxicity would be superceded by the 90-day, developmental toxicity, and the reproduction and fertility effects studies if finalized in the CHTR. The cost of testing a particular chemical substance would be dependent on which tests are needed for that chemical as identified in the CHTR. A thorough analysis of costs will be presented in the proposed rule documentation.

In a recent Federal Register notice, (64 Fed. Reg. 2486, January 14, 1999), EPA requested public comments on the Agency's proposed Information Collection Request (ICR) for section 12(b), the export notification provision of TSCA. In that Federal Register notice, EPA provided background information regarding the HPV Challenge Program and associated TSCA section 4 test rulemaking activity, and stated that the TSCA section 12(b) export notice

requirements pertain to chemicals listed in proposed and final TSCA Section 4 test rules. EPA also stated in the Federal Register notice that the section 12(b) export notification requirements apply to those who are engaged in the "wholesale sale" of chemical substances and mixtures. Are these statements correct?

No, not entirely. EPA's TSCA section 12(b) export notification regulations, 40 CFR 707, subpart D, require any person who exports or intends to export a chemical substance or mixture to notify EPA of such export if any of the following actions have been taken under TSCA with respect to that chemical substance or mixture: (1) data are required under section 4 or 5(b); (2) an order has been issued under section 5; (3) a rule has been proposed or promulgated under section 5 or 6; or (4) an action is pending or relief has been granted under section 5 or 7. See 40 CFR 707.60(a). With regard to section 4, only persons that export or intend to export chemical substances or mixtures covered by final TSCA section 4 test rules or enforceable consent agreements (ECAs) are subject to the section 12(b) export notification requirements. Further, only persons that export or intend to export subject chemical substances and mixtures are required to submit TSCA section 12(b) notices to the Agency; the "wholesale sale" of chemical substances is not a criterion for determining whether a person is required to submit an export notice under section 12(b).

Note: For additional information about EPA's TSCA section 12(b) regulations (which also cover, for example, the export of PCBs and PCB articles), see 40 CFR 707 subpart D, as well as 45 Fed. Reg. 82844 (December 16, 1980), 49 Fed. Reg. 45581 (November 19, 1984), 58 Fed. Reg. 40242 (July 27, 1993), and 58 Fed. Reg. 40242 (December 27, 1993).

As the March 15 deadline is almost here, I would like to send my response letter to Carol Browner either by express/overnight mail or by courier to the Agency. Is there a street address I can use instead of the PO box? May I also send the response letter to EPA via fax?

A response letter may either be express/overnight mailed or sent by courier to the Agency at the following address:

U.S. Environmental Protection Agency
401 M Street, S.W.; Mail Code: 7405
Washington, D.C. 20460

The contact name is Charles Auer and the phone number is 202-260-3749. Those who wish to fax their letter may do so by using the following fax number: 202-260-8168 and addressing the fax to Charles Auer. Please note that the original letter with authorized signature must follow the fax as soon as possible and must be sent to the original post office address: US EPA; PO Box 1473; Merrifield, VA 22116. Attn: Chemical Right-to-Know Program.

What is the High Production Volume (HPV) Challenge Program?

The HPV Challenge Program is a key element of the Chemical Right-to-Know initiative announced this year, on the eve of Earth Day, by Vice President Gore and EPA Administrator Carol Browner.

As part of this initiative, EPA, in partnership with industry and environmental groups, created a major ground breaking voluntary chemical testing effortùthe HPV Challenge Program. This program was developed to make publicly available a complete set of baseline health and environmental effects data on HPV chemicals. This data is to be collected for each chemical on EPA's list of HPV chemicals (defined as those manufactured in, or imported into, the United States in amounts equal to or exceeding 1 million pounds per year). Testing will be necessary only when existing data are not adequate. The program will generally be carried out in a manner consistent with the internationally-recognized testing protocol (as developed by the Organization for Economic Co-operation and Development (OECD) Screening Information Data Set (SIDS) program) to ensure that the testing can be contributed to the international effort and, conversely, that international SIDS testing and assessments can be used to fulfill the Challenge Program's requirements. The data generated through this program will be made available to the public, fulfilling the EPA's commitment to the public's right-to-know.

What are the benefits of signing up for this voluntary program?

Signing up for the Challenge Program provides an opportunity for recognition as an industry leader on an issue of importance to the public. In the spirit of this right-to-know initiative, the Agency would like to publicly recognize those companies participating in the HPV Challenge Program on its Web Site http://www.epa.gov/opptintr/chemrtk .

Companies with active product stewardship programs recognize the real importance of filling basic data needs on the chemicals they produce. Much, if not most, of this data can be made available by building voluntary partnerships between EPA and industrial leaders, thus avoiding the necessity for writing rules to obtain test data on HPV chemicals. In addition, the voluntary program allows the use of chemical category approaches which provide some flexibility in the tests to be conducted on each chemical in the category; the test rule will not allow that flexibility. Additionally, the outputs of the voluntary program will be detailed study summaries; the test rule will require submission of entire studies for each of the SIDS test needed for each chemical. top

How can a company participate in the HPV Challenge Program?

Participating in the Challenge Program involves sponsoring HPV chemicals from the list published on the EPA's Chemical Right-to-Know web site http://www.epa.gov/opptintr/chemrtk/hpvchmlt.htm

Sponsors pledge to evaluate the adequacy of existing data and to conduct tests where needed to fill the gaps in the data. A company need not have already performed a detailed review of existing data before making a commitment; this would be provided by sponsoring companies at a later date along with a more detailed testing plan. Companies wishing to participate in the HPV Challenge Program can do so by submitting (on paper, or electronically) a letter of commitment to EPA which identifies the chemicals they will test and a planned start year for the testing. The mailing address for this letter is: Carol Browner, Administrator, US EPA, PO Box 1473, Merrifield, VA 22116, Attn: Chemical Right-to-Know Program. The process for electronic submission of commitments is being finalized, and will soon be made publicly available. Check the Chemical Right-to-Know Web Site http://www.epa.gov/opptintr/chemrtk for updates. Suggested sample language for this letter of commitment can also be found at the Chemical Right-to-Know Web Site. (

http://www.epa.gov/opptintr/chemrtk/sugdlang.htm)

Will EPA publish a list of the companies that participate in the voluntary component of the program?

EPA plans to publish a list of participating companies with their permission.

Which chemicals are on the HPV chemical list?

The HPV chemical list is based on the list developed as a result of the Toxic Substances Control Act (TSCA) Inventory Update Rule (IUR) of 1990. EPA has, however, identified some chemicals which are not considered candidates for testing under the HPV Challenge Program based on preliminary EPA review indicating no need for baseline testing. The final list of chemicals can be found on the EPA's Chemical Right-to-Know web site at http://www.epa.gov/opptintr/chemrtk/hpvchmlt.htm .

How often will the HPV chemical list be updated?

The list of chemicals covered by the HPV Challenge Program will not change appreciably once the Program is launched. EPA anticipates that creating baseline health and environmental test data will eventually become routine for newly-identified HPV chemicals, through a combination of domestic and international testing activities. Although newly identified HPV chemicals will not be a part of the HPV Challenge Program, EPA will evaluate the data needs for these chemicals and begin dialogue with domestic manufacturers and OECD SIDS participants to ensure that the information needed for these HPVs is developed in a timely fashion.

What does it mean that the data generated through this program will be available to the public? How will confidential business information (CBI) be handled?

The principle that the public has a fundamental right to know about the hazards associated with chemicals in commerce is central to this initiative. For this reason, EPA intends to ensure that the information created through the HPV Challenge Program is broadly available to the public, chiefly through the Internet. Therefore, EPA encourages electronic submission of data to facilitate making this information widely accessible and strongly discourages submission of confidential business information. EPA's Chemical Right-to-Know web site http://www.epa.gov/opptintr/chemrtk will house much of the information for the Challenge Program.

What is the relationship between the HPV Challenge Program and any subsequent rulemaking under the Toxic Substances Control Act (TSCA)?

EPA plans, if necessary, to make those HPV chemicals not sponsored in the Challenge Program subject to a test rule under Section 4 of the Toxic Substances Control Act (TSCA). Companies that have committed to the program before February 1, 1999 can be assured that sponsored HPV

chemicals will not be listed on the proposed test rule. Companies will still have an opportunity to commit to the HPV Challenge Program after the publication of the proposed rule. The program will remain open until December 1, 1999, shortly before the promulgation of the final rule. In addition, although testing chemical categories (instead of each individual chemical) will be encouraged in the Challenge Program, this approach will not be included under the test rule. Inclusion of a chemical in the Test Rule will also trigger TSCA Section 12(b) export notification requirements.

What do you mean by "chemical categories"?

A chemical category is a group of related chemicals that lend themselves to evaluation and testing as a group. The chemicals can be grouped based on similarities in chemical structure or functionality. If testing is strategically planned, less than the full number of tests for each individual chemical will be necessary and testing costs will be reduced. Examples of categories might include simple (e.g., C 1-6) organic acids and their labile salts, fatty alcohols, or aliphatic aldehydes. EPA is working closely with stakeholders to develop a guidance document on categories for use in the Challenge Program. This document will be made available on the EPA's Chemical Right-to-Know web site http://www.epa.gov/opptintr/chemrtk .

Where can a company find guidance for the tests included in the HPV Challenge Program?

General guidance on participation can be found in the "Principles for Participation in the High Production Volume Challenge Program," available from EPA through its TSCA Hotline at 202-554-1404, or through the web site at http://www.epa.gov/opptintr/chemrtk/guidance.htm . The baseline hazard information has been defined by the Organization for Economic Cooperation and Development (OECD) in its Screening Information Data Set (SIDS). SIDS represents an internationally agreed upon set of tests to screen chemicals and identify potential hazards. The basic screening endpoints to be tested are: acute toxicity, chronic toxicity, developmental and reproductive toxicity, mutagenicity, ecotoxicity, environmental fate, and physical-chemical properties, and are listed in Section 2.2 (page 2) of "Screening Information Data Set Manual of the OECD Programme on the Co-operative Investigation of High Production Volume Chemicals," published in July, 1997. This manual (also called the "SIDS Manual") is available at http://www.epa.gov/opptintr/sids/sidsman.htm , or obtained as hard copy from OECD Environment Directorate, Environmental Health and Safety Division; 2, rue Andre-Pascal F-75775; Paris Cedex 16, France. Tel: 331-1-4524 9844. Specific information on the SIDS test protocols can be found at: http://www.oecd.org/ehs/hpv.htm

How much will it cost per chemical to complete a full battery of SIDS testing?

EPA projects that the full battery of tests and estimations included in the SIDS testing will cost approximately $250,000 per chemical, assuming that none of the SIDS data are available. Any adequate existing SIDS test data will reduce these costs accordingly. For a further breakdown of costs, please refer to Table 8 in EPA's Chemical Hazard Data Availability Study at http://www.epa.gov/opptintr/chemtest/hazchem.htm .

Can a company share the cost with other manufacturers of the same chemicals?

Yes, EPA encourages companies to work together to avoid duplicative testing efforts. However, when cooperating on testing, companies are advised to bear in mind any restrictions imposed by federal antitrust laws.

Will there be enough laboratory capacity to complete the required testing?

Based on the results of the 1996 "EPA Census of TSCA Testing Laboratories ù Final Report" and an assessment of the SIDS testing requirements, EPA believes that there is adequate laboratory capacity to meet most if not all of the demand for testing the HPV chemicals. This report is available through the TSCA Hotline, at 202-554-1404. The timeframe of the Program is adequate for national laboratory capacity to grow to meet any testing demands created by the Challenge Program.

Can companies negotiate the methods for testing with EPA? Will other methodologies besides those found in the SIDS manual meet the EPA's criteria?

The full set of SIDS test data is needed, although exceptions can be made in special circumstances (for example, if chemical instability or reactivity or water solubility prevents carrying out a specific test). In such cases, modifying study procedures or dropping specific tests where circumstances warrant may be appropriate. Testing should be done according to OECD test guidelines Testing should be done according to OECD test guidelines http://www.oecd.org/ehs/test/testlist.htm). The SIDS manual can be obtained on the Internet at http://www.epa.gov/opptintr/sids/sidsman.htm , http://www.oecd.org/ehs/hpv.htm or as hard copy from OECD Environment Directorate, Environmental Health and Safety Division; 2, rue Andre-Pascal F-75775; Paris Cedex 16, France. Tel: 331-1-4524-9844.

How will the data from the testing be used? What are the steps for Agency decisions once test data has been submitted?

The intent of EPA's HPV Challenge Program is to gather a basic set of environmental and health effects data for each chemical and make this data publicly available and thereby improve the public's understanding of the toxicity of chemicals most commonly used in this country. The database resulting from this activity will be adequate to support a screening level hazard characterization, which is the first step toward what is known as a risk assessment. Using this hazard characterization on a given chemical with information about its uses and exposures, EPA and others will then be able to better characterize the potential for adverse human health or environmental effects and decide if further testing or other action is necessary.

Are pesticide inert chemicals included in this HPV Challenge Program?

Yes. If you have conducted testing on your product for EPA's Office of Pesticide Programs, that data may be relevant to the HPV Challenge Program.

Some HPV chemicals were tested years ago. Are these tests still valid?

Tests conducted according to appropriate OECD Test Guidelines (as noted in the SIDS Manual

available at http://www.oecd.org/ehs/hpv.htm) or comparable EPA test guidelines are acceptable. Older studies should be compared to these test guidelines to identify differences in testing procedures and to gauge their possible acceptability.

EPA is developing a data adequacy guidance document for this purpose. This document will be made available through the EPA's Chemical Right-to-Know web site at http://www.epa.gov/opptintr/chemrtk . If existing data are determined to be adequate, companies sponsoring a chemical will only need to make these data publicly available by submitting it in summary form to EPA.

How can I find out how much hazard information is currently available on each HPV chemical?

You can find EPA's HPV chemical-hazard information matrix corresponding to the SIDS endpoints at http://www.epa.gov/opptintr/chemtest/hazchem.htm#master . This matrix captures the publicly available information on the HPV chemicals. The Chemical Manufacturers Association published a study entitled "Public Availability of SIDS-Related Testing Data For U.S. High Production Volume Chemicals," June 12, 1998, which may be obtained by contacting the Chemical Manufacturers Association (703-741-5226).

How will the Challenge Program affect small businesses?

EPA is well aware that some of the HPV chemicals are manufactured or imported by small and mid-sized chemical companies. The HPV Challenge Program has been crafted to be flexible and responsive to the concerns of the many different companies and organizations that comprise the chemical industry. Our dialogues with companies and trade organizations have identified particular concerns of small manufacturers, and we have explored adjustments to the Challenge Program to accommodate the needs of small business. We will continue this constructive dialogue as the HPV Challenge Program matures, to ensure that small business concerns are well-represented.

All documents named above can also be obtained in hard copy through regular mail by calling the TSCA Hotline at 202-554-1404. The toll-free number has been discontinued.